Cell Banking
Investing in GMP-Compliant Manufacturing of Biopharmaceuticals

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If you can’t do it right the first time, then don’t do it at all…. 

The quality of biopharmaceuticals depends on the quality of cells used for production. 

- Cross-contamination with another cell line 
- Contamination with bacteria, fungi, virus 
- Identity and integrity of expression construct of recombinant cell lines.
Who’s being protected from What?

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Center of Excellence for Regenerative Health Biotechnology
Introduce Foreign Gene that expresses Protein Product (Therapeutic)

Screen for expression of foreign gene

Pick one

Bacterial Lawn

Seed Cell Bank
20 vials
1x10^7 cells/vial

Producer Cell Clone
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Master Cell Bank

- A well characterized cell bank in accordance with regulatory standards (21 CFR 610)
- Master cell bank established from single clone
- Quality established from master bank to production and end-of-production cells
- Master cell bank represents a cell reserve ‘frozen-in-time’
  - Preserves characteristics
  - Prevents contamination and deterioration
GMP Manufacturing
Master Cell Bank & Working Cell Bank

A two tiered frozen cell bank

--- Raw Materials ---

Seed Cell Bank
20 vials
1x10^7 cells/vial

Master Cell Bank
200 vials
$100,000

Working Cell Bank
200 vials
$40,000

Production

• Working cell bank: cells from one vial of the master bank which have been grown for several passages before storage.

• When future cells are needed, they are taken from the working cell bank.

• The Master cell bank is used only when absolutely necessary, ensuring a stock of cells with a low passage number to avoid genetic variation within the cell culture.
• Stored in two or more locations. One is off-site.

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Characterization of Master Cell Bank

Confirmation of:

1) Identity – Cells and their expression construct are what they are intended to be.
2) Purity – Test for the presence of contaminating cell lines, viruses, mycoplasma, and bacteria.
3) Stability – Cell viability and stability of coding region (for recombinant cell banks) must be determined during cultivation and storage.
Production Process

- WCB
- Expand for Production
- Harvest
- Lyse
- Purify
- Formulate
- Store
- Ship
- Final Product Testing

stability  safety  purity  potency
sterility  adventitious agents
Product Pathway

- Discovery research
- Pre-clinical research
- Clinical research
- Drug, Device, and Diagnostic product development
- Process and Assay Development
- Manufacturing and Testing

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